K011033

JUN - 7 2001

DADE BEHRING

DADE BEHRING INC.
P.O. Box 6101
Newark, DE 19714

Summary of Safety and Effectiveness Information

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Submitter's Name:	Richard M. Vaught Dade Behring Inc. P.O. Box 6101 Newark, DE 19714-6101
Date of Preparation:	April 4, 2001
Name of Product:	Dade Behring Dimension® Lithium (LI) Flex® reagent cartridge
FDA Classification Name:	Lithium test system
Predicate Device:	Ion Selective Electrode(ISE), Lithium Method on the Ciba Corning Model 654 Analyzer (K884769)
Device Description:	The Dade Behring Dimension® Lithium (LI) Flex® reagent cartridge is an *in vitro* diagnostic device that consists of prepackaged reagents in a plastic cartridge for use only on the Dimension® clinical chemistry system.
Intended Use:	The Dimension® Lithium (LI) Flex® reagent cartridge is an *in vitro* diagnostic test intended for the quantitative determination of lithium in serum and plasma (sodium heparin).

Comparison to Predicate Device:

The Dimension® Lithium (LI) Flex® reagent cartridge is substantially equivalent to other lithium assays such as the Lithium ISE method on the Ciba Corning 654 (ISE) analyzer. A comparison of the features of these products is provided in the following chart:

Feature	Dade Behring Dimension® LI Flex® method	Lithium ISE Method (Ciba Corning Model 654)
Intended Use	*in vitro* use	*in vitro* use
Sample size	10 uL	65 uL
Measurement	Bichromatic endpoint; 540 nm and 700nm	Potentiometric; ion selective electrode
Assay range	0.2 - 5.0 mmol/L	0.2 - 5.0 mmol/L
Assay Temperature	37° C	10° C to 32° C

Comments on Substantial Equivalence:

Split sample comparison between the Dimension® LI Flex® reagent cartridge method and the Lithium ion selective electrode(ISE) method on the Ciba Corning 654 analyzer gave a correlation coefficient of 0.998, a slope of 1.01 and an intercept of -0.02 when tested with 128 clinical patient samples ranging from 0.24 to 3.60 mmol/L.

Conclusion:

The Dimension® LI Flex® reagent cartridge method and the Lithium ion selective electrode(ISE) method are substantially equivalent in performance based on method split sample comparisons.

RM Vaught

Richard M. Vaught
Regulatory Affairs and Compliance Manager
Date: April 4, 2001

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN - 7 2001

Mr. Richard M. Vaught
Regulatory Affairs and Compliance Manager
Dade Behring Inc.
Glasgow Business Community
Bldg. 500, M.S. 514
P.O. Box 6101
Newark, DE 19714

Re: 510(k) Number: K011033
Trade/Device Name: Dimension® Lithium (LI) Flex® Reagent Cartridge
Regulation Number: 862.3560
Regulatory Class: II
Product Code: JIH
Dated: April 4, 2001
Received: April 5, 2001

Dear Mr. Vaught:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications For Use Statement

510(K) NUMBER: K011033

Device Name:

Dimension® Lithium (LI) Flex® reagent cartridge

Indications for Use:

The Dade Behring Dimension® Lithium (LI) Flex® reagent cartridge is an *in vitro* diagnostic tested intended for the quantitative determination of lithium in serum and plasma (sodium heparin). Measurements of lithium are used to assure that the proper drug dosage is administered in the treatment of patients with mental disturbances, such as manic-depressive illness (bipolar disorder).

R M Vaught

Richard M. Vaught
Regulatory Affairs and Compliance Manager

April 4, 2001

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Fred Lacy

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K011033

Prescription Use X **OR** **Over-the-counter Use** _____
(Per 21 CFR 801.109)

(Optional format 1-2-96)